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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,769	09/22/1999	ERIK HELMERHORST	28594/35007A	3787

7590 11/29/2002

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/29/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/400,769**

Applicant(s)  
**Helmerhorst et al.**

Examiner  
**Hope Robinson**

Art Unit  
**1653**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 15, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-31 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 20-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

1. Applicant's response to the Office Action mailed June 12, 2002 in Paper No. 22 on September 18, 2002 is acknowledged.
2. Claims 18 and 19 have been canceled. Claims 1, 5, 6 and 11 have been amended. Claim 20-31 have been added. Claims 1-17 and 20-31 are pending and are under examination.
3. The rejection under 35 U.S.C. 101 has been withdrawn. The following rejections are or remain applicable:

### ***Information Disclosure Statement***

4. The information disclosure statement filed on 12/27/99 still fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because the items listed on pages 1-9 of the information disclosure statement are missing from the application.

Correction is required.

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***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17 remain rejected and claims 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite because the claim recites the term “biological modulator” and it is unclear if applicant intends modulate to mean increase or decrease (see also claim 11). Note that only one of these terms should be recited in the claim. The claim is further indefinite for the recitation of “associated” because it is unclear what type of association exists between the amino acids and the binding of insulin to its receptor as the claim does not explicitly state the so called “association” (see also claim 16). Claim 1 is also indefinite for the recitation of “insulin related ailments”, as the metes and bounds of the claim is not clear, as to what is considered to be an “insulin related ailment” that will be treated by the claimed method.

Claims 2 and 4 are indefinite for the recitation of “selected from the group comprising” as this is improper markush language and the word comprising is open which means that there are items not listed that could be in the group.

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Claim 6 as amended is indefinite because the deleted portions of the claim now leaves the following : “5R<sub>1</sub> groups,;” (see for example lines 8, 9, 12 and 13 of the claim).

Claims 20-31 are indefinite for the recitation of “selected from the group” rather than “selected from the group consisting of”, which is the proper markush claim language (see also claim 10.

6. Applicant’s response filed September 18, 2002 in Paper No. 22 has been considered, however, the rejections under 35 U.S.C. 112, second paragraph remains. Note also that the Information Disclosure Statement remains objected to despite applicant’s comments as the references are not present in the application, thus, cannot be reviewed. It is suggested that applicant resubmit copies of the references if applicant would like them to be considered. With regard to the rejection under 35 U.S.C. 112, second paragraph, applicant contends that the term “modulate” is definite because one skilled in the art reviewing the specification would understand the meaning of this term as used in the claims. This argument is not convincing as applicant states that the term as used refers to a compound that can be an agonists or antagonists. Thus, this exemplifies the ambiguity of the claim as the two actions are opposed and should not be recited in the same claim. It is suggested that applicant claim only one action for the term modulate. Furthermore, the limitations of the specification cannot be read into the claim. Therefore, for the

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reasons stated above applicant's comments are not persuasive. Note also that new grounds of rejections have been instituted based on the submission of new claims.

### *Conclusion*

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.


Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

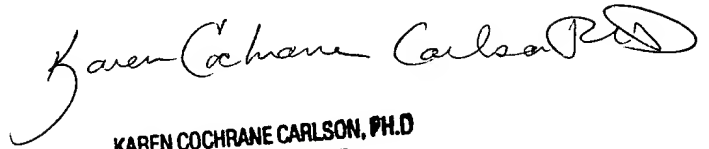
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Hope A. Robinson, MS 

Patent Examiner

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER